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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,866	03/03/2004	Robert Frederick Veasey	02481.1840	3124
22852	7590	03/14/2006	EXAMINER	
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413			PRASAD, SONAL	
			ART UNIT	PAPER NUMBER
			3767	

DATE MAILED: 03/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

SR

<b>Office Action Summary</b>	<b>Application No.</b> 10/790,866	<b>Applicant(s)</b> VEASEY ET AL.	
	<b>Examiner</b> Sonal Prasad	<b>Art Unit</b> 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 March 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>5/18/05</u> <u>12-4-05</u> <u>12-4-05</u> | 6) <input type="checkbox"/> Other: ____  |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1- 3,5-10,12-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Burroughs et al (US 6,221,046 B1). Burroughs et al. discloses a drive mechanism for use in a drug delivery device (abstract lines 17-22), housing having an internal helical thread (col 20, lines 65-67), a dose dial sleeve having a helical thread engaged with the helical thread of the housing (abstract lines 6-13), a drive sleeve releasably connected to the said dose dial sleeve (col 4, lines 44-46), and a clutch means located between the dose dial sleeve and the drive sleeve; the clutch means configured such that (col 10, line 9), a) when the dose dial sleeve and the drive sleeve are coupled, both are allowed to rotate with respect to the housing, and b) the dose dial sleeve with respect to the housing is allowed, whilst while rotation of the drive sleeve with respect to the housing is prevented , whereby axial when the dose dial sleeve and the drive sleeve are de-coupled, rotation of movement of the drive sleeve is allowed so that a force is transferred in the longitudinal direction to a proximal end of the drug delivery device. (Fig. 1, #34)

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Regarding claim 2, Burroughs et al. discloses a drive mechanism comprising a piston rod adapted to operate through the housing and transfer the said force in the said longitudinal direction to the proximal end of the drug delivery device. (Fig. 1, #210, summ 11).

Regarding claim 3, Burroughs et al. discloses the drive mechanism wherein said dose dial sleeve further comprises a helical thread, which has the same lead as the lead of the helical thread of the said drive sleeve. (claim 19, Fig. 1)

Regarding claims 5 & 6, Burroughs et al. discloses the drug delivery device as described above. (abstract line 1)

Regarding claims 7 & 15, Burroughs et al. discloses a drug delivery device wherein the delivery device is a pen-type device. (abstract line 1)

Regarding claims 8 & 16, Burroughs et al. discloses a drug delivery device wherein the delivery device is an injector-type device. (summ 6, line 3)

Regarding claims 9 & 17, Burroughs et al discloses the delivery device comprising a needle. (Fig. 1, #44)

**Claim 11 has been canceled by the applicant.**

Regarding claim **12**, Burroughs et al. discloses the method wherein dispensing a medicinal product includes dispensing a pharmaceutical formulation comprising an active compound selected from the group consisting of insulin, growth hormone, low molecular weight heparin, analogues thereof, and derivatives thereof. (summ 5, line 10)

Regarding claim **19 & 22**, Burroughs et al. discloses a method of delivering a drug, comprising providing the device dispensing a medicinal product with the device. (col 3, line 10)

Regarding claim **20 & 21**, Burroughs et al. discloses the method wherein dispensing a medicinal product includes dispensing a pharmaceutical formulation from the device, wherein the pharmaceutical formulation comprises an active compound selected from the group consisting of insulin, growth hormone, low molecular weight heparin, analogues thereof, and derivatives thereof. (col 3, line 10)

Regarding claims **10 & 18**, Umbaugh (US 6,083,197) discloses the same device with a needle- free device. (Claim 1.)

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over

Burroughs et al (US 6,221,046 B1) in view of Sams (US 6,899,698 B2.)

Claim 4 differs from Burroughs et al in disclosing the toothed gear. Sams discloses the drive mechanism wherein the said piston rod is designed to have attached a toothed gear designed to mesh with the threads of the drive sleeve and the teeth of a toothed rack, whereby the teeth of a toothed rack is fixed to the housing. (abstract, summ 11, and Fig. 1, #30). It would have been obvious at the time of invention to one of ordinary skill in the art to include the toothed gear as disclosed in Burroughs et al as taught by Sams to improve function within the housing.

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sonal Prasad whose telephone number is 571-272-3383. The examiner can normally be reached on M-F.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sonal Prasad  
Examiner  
Art Unit 3767



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